Reviewer: Rick J. Whiting **Date: February 15, 2011**
Risk Manager (EPA): 23

STUDY TYPE: Primary Dermal Irritation - Rabbit; OCSPP 870.2500; OECD 404

TEST MATERIAL: GF-2633 (Triisopropanolamine salt of Aminopyralid – 8.28 wt%; 2,4-D, dimethylamine salt – 42.2 wt%; Lot No. F1506-50, TSN032903-0001; pH: 7-8; soluble in water; clear liquid)

CITATION: Durando, J. (2010) GF-2633: Primary Skin Irritation Study in Rabbits. Project Number: 101015, 29304. Unpublished study prepared by Eurofins/Product Safety Laboratories. 31 p. July 1, 2010. MRID 48173007

SPONSOR: The Dow Chemical Company, Midland, MI 48674

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 48173007), three young female adult New Zealand White rabbits (age: 11 weeks; weight: 2014-2380 g; source: Robinson Services, Inc., Clemmons, NC) were dermally exposed to GF-2633 (Triisopropanolamine salt of Aminopyralid – 8.28 wt%; 2,4-D, dimethylamine salt – 42.2 wt%; Lot No. F1506-50, TSN032903-0001; pH: 7-8; soluble in water; clear liquid). Five-tenths of a milliliter of the test material as received was applied to one 6 cm^2 intact dose site on each animal and covered with a 1-inch x 1-inch, 4-ply gauze pad. The pad and trunk were wrapped with semi-occlusive Micropore tape. Elizabethan collars were placed on the rabbits. After 4 hours of exposure, the pads and collars were removed and the test sites were gently cleansed with a 3% soap solution then tap water and a clean towel to remove any residual test material. Individual test sites were scored according to the Draize scoring system (1944) at approximately 30-60 minutes, 24, 48, and 72 hours after patch removal.

Well-defined erythema (score of 2) was observed at all three test sites at 1 hour and 24 hours. Very slight erythema (score of 1) was observed at all three test sites at 48 hours. Slight edema (score of 2) was observed at all three test sites at 1 hour and at one test site at 24 hours. Very slight edema (score of 1) was observed at two test sites at 24 hours. All dermal irritation was resolved by 72 hours. The Primary Dermal Irritation Index (PDII) is 2.08 based dermal irritation scores from 1 hour to 72 hours.

In this study, the formulation was moderately irritating. GF-2633 is classified as EPA Toxicity Category IV for primary dermal irritation.

This study is classified as Acceptable. It does satisfy the guideline requirement for a primary dermal irritation study (OCSPP 870.2500; OECD 404) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

A. Observations: Well-defined erythema (score of 2) was observed at all three test sites at 1 hour and 24 hours. Very slight erythema (score of 1) was observed at all three test sites at 48 hours. Slight edema (score of 2) was observed at all three test sites at 1 hour and at one test site at 24 hours. Very slight edema (score of 1) was observed at two test sites at 24 hours. All dermal irritation was resolved by 72 hours.

INDIVIDUAL SKIN IRRITATION SCORES

ERYTHEMA/EDEMA

Animal No.	Sex	Hours After Patch Removal			
		1	24	48	72
3501	F	2/2	2/2	1/0	0/0
3502	F	2/2	2/1	1/0	0/0
3503	F	2/2	2/1	1/0	0/0
Severity of Irritation - Mean Score		4.0	3.3	1.0	0.0

B. Results: The Primary Dermal Irritation Index (PDII) is 2.08 based dermal irritation scores from 1 hour to 72 hours.

C. Reviewer's Conclusions: TRB agrees with the study author's conclusions. Based on the, is classified as EPA Toxicity Category IV.

D. Deficiencies: None.